

REMARKS

Favorable consideration and allowance are respectfully requested for claims 2, 3, 9-15 and 17.

The Examiner is thanked for the careful review and consideration of the present application and, in particular, the withdrawal of numerous objections and rejections of the claims.

The rejection of claims 2, 3 and 9-15 under 35 U.S.C. § 112, second paragraph, as indefinite for reciting the phrase "84% homology" is respectfully traversed. This phrase has been deleted from claim 2. In view of this amendment, reconsideration and withdrawal of the rejection of claims 2, 3 and 9-15 as indefinite is respectfully requested.

Claim 2 has been amended so that it is directed to a DNA fragment comprising the nucleotide sequence given in SEQ ID NO: 14, or a sequence that hybridizes under stringent conditions to a hybridization probe the nucleotide sequence of which consists of SEQ ID NO: 14 or the complement of SEQ ID NO: 14, wherein said DNA fragment has a function to encode polypeptides necessary to produce aclacinomycins. The stringent conditions of the hybridization are particularly set forth on page 4 of the specification beginning at line 18.

New claim 17 is provided in this amendment. This claim depends from claim 2 and further clarifies the "stringent conditions" set forth in claim 2. This claim is supported by page 4 of the specification, beginning with line 18.

The rejection of claim 13 under 35 U.S.C. § 112, second paragraph, as indefinite for the phrase “anthracycline metabolites” is respectfully traversed. Claim 13 is amended to replace the phrase “anthracycline metabolites” with the term “polyketides”. Accordingly, the indefiniteness rejection is no longer applicable and withdrawal thereof is respectfully requested.

The rejection of claims 14 and 15 under 35 U.S.C. § 112, second paragraph, as indefinite for the terms “activator” and “polyketide assembler” is respectfully traversed. Claims 14 and 15 have been amended to delete references to the polyketide assembler. The Examiner is urged to reconsider allowing claim 15 with the term “activator” because a person of skill in the art would clearly understand the claim language, as amended, to indicate that the DNA fragment comprises a gene sequence that encodes a protein structure active as an activator. Moreover, the term “activator” has a clear and definite meaning to a person of skill in the art, especially considering the context of polyketide biosynthesis. It is well known in the art that the polyketide biosynthetic pathways include pathway-specific activators. Accordingly, reconsideration and withdrawal of this rejection are requested.

The rejection of claims 2, 3 and 9-15 under 35 U.S.C. § 112, first paragraph, with respect to the written description requirement, is respectfully traversed. The Examiner suggested inserting functional language to describe the “sequence showing at least 84% homology to said sequence” to overcome this rejection. In response, claim 2 has been amended to recite that “said DNA fragment has a function to encode polypeptides necessary to produce

aclacinomycins.” Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claims 2, 3 and 9-15 under 35 U.S.C. § 112, first paragraph, as lacking enablement in reciting 84% homology is respectfully traversed. As indicated above, the claims no longer recited the 84% homology limitation. The claims are believed to be properly enabled, and reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claims 9, 11 and 14 under 35 U.S.C. § 112, first paragraph, for lack of enablement because the specification allegedly does not provide enablement for methods of increasing or producing aclacinomycins in all *Streptomyces* hosts is respectfully traversed. As amended, claim 2 clearly recites that the DNA fragment is functional to encode polypeptides necessary to produce aclacinomycins. Accordingly, it is clear that following the DNA transfer recited in claim 9, the *Streptomyces* host is able to produce aclacinomycin. Further, the phrase “intermediates thereof” has been replaced with the term “aklavinone” in claim 9. This amendment is supported in the specification at least on page 5, line 17. Accordingly, the method relates to increasing aclacinomycin production in a *Streptomyces* host that produces aclacinomycin or aklavinone. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 9-11, 13 and 14 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite for reciting the term “intermediates”. In response, the phrase “intermediates thereof” has been replaced with the clear and definite

Application No. 09/830,994
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term "aklavinone" in claims 9 and 13. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

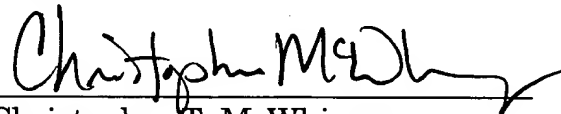
CONCLUSION

In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited. If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029381.49884US).

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Respectfully submitted,



Christopher T. McWhinney
Registration No. 42,875

Herbert I. Cantor
Registration No. 24,392

CROWELL & MORING LLP
Intellectual Property Group
P.O. Box 14300
Washington, DC 20044-4300
Telephone No.: (202) 624-2500
Facsimile No.: (202) 628-8844

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